# RECEIVED

NOV 0 7 2003

Sheet 1 of 5

EXPRESS MAIL NO. EL 501 638 985 US

TECH CENTER 1600/2900

APPLICATION NO. 09/645,415 8002-059-999 APPLICANT Bermudes et al. GROUP FILING DATE

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) 164-1632 August 24, 2000 U.S. PATENT DOCUMENTS SUBCLASS FILING DATE CLASS DOCUMENT NUMBER NAME 'EXAMINER INITIAL APPROPRIATE PR 4,436,727 Ribi 3/13/84 AA 5,021,234 6/4/91 Ehrenfeld AB 9/6/94 Karapetian AC 5,344,762 AD 5,824,538 10/20/98 Branstrom 9/10/97 Bermudes et al. AE 6,080,849 12/7/99 Powell et al. EΚ 5,997,881 RUS EL 6,150,170 11/21/00 Powell et al. 8/24/00 Bermudes et al. EM 09/645,418 3/2/99 Powell et al. ES 5,877,159 **FOREIGN PATENT DOCUMENTS** SUBCLASS CLASS TRANSLATION OATE DOCUMENT NUMBER RRS PCT AF 5/16/91 WO 9106317 WO 9211361 7/9/92 PCT AG PCT WO 9502048 1/19/95 AH AI WO 9611277 4/18/96 PCT WO 9640238 12/19/96 PCT ΑJ 5/29/97 PCT WO 9718837 AK 6/5/97 PCT AL WO 9719688 PCT AM WO 9725061 7/17/97 8/16/98 PCT WO 9833923 AN EN WO 9634631 11/7/96 PCT PCT EO WO 9718225 5/22/97 EP WO 9853854 12/3/98 PCT EQ WO 9913003 3/18/99 **PCT** PCT 12ns WO 9952563 10/21/99 ER OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.) Rns Adler, 1973, "A Method for Measuring Chemotaxis and Use of the Method to Determine Optimum Conditions for Chemotaxis by Escherichia coli", J. Gen. Microbiol. 74:77-91.

Alizadeh et al., 1994, "Apoptosis as a Mechanism of Cytolysis of Tumor Cells by a Pathogenic Free-Living Amoeba", Infect. 2100 Immun, 62:1298-1303.

2/6/04

# RECEIVED

#### NOV 0 7 2003

**TECH CENTER 1600/2900** 

Sheet 2 of 5

CCT		چ	<u>TECH CENTER 1600/2900</u>
rent !	13	MARTE	Anderson et al., 1996, "Development of attenuated Salmonella strains that express heterologous antigens", Methods in Molecular Medicine: Vaccine protocols, ed. Robinson A, Farrar G, Wiblin C., Hurnana Press New Jersey, pp.47-62
CALS MADE			Bagshawe, 1995, "Antibody-Directed Enzyme Prodrug Therapy: A Review", Drug Dev. Res. 34:220-230.
1 /		AS	Barry et al., 1995, "Protection Against Mycoplasma Infection Using Expression-Library Immunization", Nature 377:632-635.
AT			Barth and Morton, 1995, "The Role of Adjuvant Therapy in Melanoma Management", Cancer 75 (Suppl.):726-734.
-AU			Berggren, 1995, "Recombinant Salmonella as an Oral HIV Vaccine", NIH Project Number 5 K08 Al01248 02.
		AV	Bermudes et al., 2000, "Tumor targeted Salmonella. Strain development and expression of the HSV TK effector gene" Gene Therapy, Methods and Protocols, Vol. 35, 419-436
П		AW	Bermudes et al., 2000, 'Tumor-targeted Salmonella. Highly selective delivery vectors', Advances in Exp. Med. And Bio. 465: 57-63
П		AX	Bone, 1993, "Gram-Negative Sepsis: A Dilemma of Modern Medicine", Clin. Microbiol. Rev. 6:57-68.
		AY	Bonnekoh et al., 1995, "Inhibition of Melanoma Growth by Adenoviral-Mediated HSV Thymidine Kinase Gene Transfer in vivo", J. Invest. Derm. 104:313-317.
		AZ	Carey et al., "Clostridial Oncolysis in Man", Eur. J. Cancer 3:37-46
		ВА	Carrier et al., 1992, "Expression of Human IL-1ß in Salmonella typhimurium; a Model System for the Delivery of Recombinant Therapeutic Proteins in vivo", J. Immunol. 148:1176-1181
		88	Carswell et al., 1975, "An Endotoxin-Induced Serum Factor that Causes Necrosis of Turnors", Proc. Natl. Acad. Sci. USA 72:3666-3670
		BC 1	Chabalgoity et al., 1996, "A Salmonella typhimurium htrA Live Vaccine Expressing Multiple Coples of a Peptide Comprising Amino Acids 8-23 of Herpes Simplex Virus Glycoprotein D as a Genetic Fusion to Tetanus Toxin Fragment C Protects Mice from Herpes Simplex Virus Infection", Mol. Microbiol. 19:791-801
		BD	Chen et al., 1999, "Liposomes complexed to plasmids encoding angiostatin and endostatin inhibit breast cancer in nude mice", Cancer Res. 59(14):Abstract.
		BE	Christ et al., 1995, "E5531, a Pure Endotoxin Antagonist of High Potency", Science 268:80-83.
		BF	Clairmont et al., 2000, "Biodistribution and genetic stability of the novel antitumor agent VNP 20009, a genetically modified strain of Salmonella typhimurium", J. Infect. Diseases 181:1996-2002
-		BG-	Clements, 1995, "Attenuated Salmonella as Vaccine Vesters", NIH Project Number 5 R01 At 28835 06.
		вн	Clementz et al., 1997, "Function of the <i>Escherichia coli msbB</i> Gene, a Multicopy Suppressor of htrB Knockouts, in the Acylation of Lipid A*, J. Biol. Chem. 272(16):10353-10360.
		ВІ	Cunningham et al., 1992, "Actin-Binding Protein Requirement for Cortical Stability and Efficient Locomotion", Science 255:325-327.
		-BJ-	Curuss, 1994, "Avirulent Salmonella Host-Vector Vaccine Systems", NIH Project Number 1 R41 Al36585-01.
		BX	Curtiss, 1995, "Biological Containment of Live Bacterial Vaccines", NHI Project Number 1 R41 Al38599 01.
		BL	Elsenstadt, 1987, "Analysis of Mutagenesis", from Escherichia coli and Salmonella typhimurium, Cellular and Molecular Biology, Neidhardt et al. (ed.), pp. 1016-1033.
	1	ВМ	Elsenstein et al., 1995, "Immunotherapy of a Plasmacytoma with Attenuated Salmonella", Med. Oncol. 12:103-108
	1	BN	Engel et al., 1992, "Murein-metabolizing enzymes from Escherichia coli: existence of a second lytic transglycosylase", J. Bacteriol. 174:6394-6403
		во	Engelbart and Gericke, 1963, "Oncolysis by Clostridia. V. Transplanted Turnors of the Harnster", Cancer Res. 24:239-243
	1	ВР	Falkow, 1991, "Bacterial Entry into Eukaryotic Cells", Cell 65:1099-1102
	1	BQ	Fields et al., 1989, "A Salmonella locus that controls resistance to microbiocidal proteins from phagocytic cells." Science 243:1059-1062
		BR	Fields et al., 1986, "Mutants of Salmonella typhimurium that cannot survive within themacrophage are avirulent". Proc. Natl Acad Sci USA, 83:5189-5193
		BS	Fox et al., 1996, "Anaerobic Bacteria as a Delivery System for Cancer Gene Therapy: in vitro Activation of 5-Fluorocytosine by Genetically Engineered Clostridia", Gene Therapy 3:173-178
1	rs	ВТ	Friberg, 1993, "BCG in the Treatment of Superficial Cancer of the Bladder: A Review", Med. Oncol. Tumor Pharmacother. 10:31-36
			2/1/10/1

RRS

2/6/04

## MEULIVEU

## NOV 0 7 2003

#### TECH CENTER 1600/2900

Sheet 3 of 5

, WI 1 4	2003	1ECH CENTER 1600/2900
PAD TRAD	BLACK	Galan et al., 1990, *Cloning and characterization of the asd gene of Salmonella typhimurium: use in stable maintenance of recombinant plasmids in Salmonella vaccine strains*, Gene 94:29-35
	BV	Galan, 1995, "Novel Salmonalla Antigen Delivery Vesters", NIH Project Number 5 R01 Al36520-02.
	вw	Gericke and Engelbart, 1963, "Oncolysis by Clostridia. II. Experiments on a Tumor Spectrum with a Variety of Clostridia in Combination with Heavy Metal*, Cancer Res. 24:217-221
	BX	Gullg, 1994, "Selmonella typhimurium Virulence Plasmid", NIH Project Number 5 R29 Al28421-05
	BY	Hall et al., 1994, "Induced Regression of Bovine Papillomas by Intralesional Immunotherapy", Therapeutic Immunol. 1:319-324
	BZ	Han et al., 1967, "Salmonellosis in Disseminated Malignant Diseases", New Eng. J. Med. 276:1045-1052.
	CA	Hoiseth and Stocker, 1981, "Aromatic dependent Salmonella typhimurium are non virulent and effective as live vaccines", Nature 291: 238-239
	СВ	Jain, 1994, "Barriers to Drug Delivery in Solid Tumors", Sci. American 271:58-65.
$\perp$	СС	Jones et al., 1992, "Invasion by Salmonella typhimurium is Affected by the Direction of Flagellar Rotation", Infect. Immun. 60:2475-2480.
	CD	Karow and Georgopoulos, 1992, "Isolation and Characterization of the Escherichia coli msbB Gene, a Multicopy Suppressed of Null Mutations in the High-Temperature Requirement Gene htrB", J. Bacteriol. 174:702-710
	CE	Kelley et al., 1993, "The firA gene o E. coli encodes UDP-3-O-(R-3-hydroxymyristoyl)-glucosamine –acetyltransferase", J. Biol. Chem. 268:19866-19874
	CF	Khan et al., 1998, "A lethal role for lipid A in Salmonella Infections", Mol. Microbiol. 29(2):571-579
	CG	King et al., 1998, "Tumor targeted Salmonella expressing cytosine deaminase converted 5-fluorocytosine to 5-fluorouricil and inhibited tumor growth in vivo", Proc. Of the Amer. Assoc. for Can. Res. 39:512
	СН	King et al., 2000, "Tumor Therapy using Salmonella", Emerging Drugs 5:211-219
	CI	Klimpel et al., 1990, "Bacteria-Infected Fibroblasts have Enhanced Susceptibility to the Cytotoxic Action of Turnor Necrosis Factor", J. Immunol. 145:711-717
	ಬ	Lee et al., 1992, "Identification of a Salmonella typhimurium Invasion Locus by Selection for Hyperinvasive Mutants", Proc. Natl. Acad. Sci. USA 89:1847-1851
	СК	Lemmon et al., 1994, "Anaerobic Bacteria as a Gene Delivery System to Tumors", Proc. Am. Assn. Cancer Res. 35:374 (Abstract 2231)
	CL	Lemmon et al., 1997, "Anaerobic Bacteria as a Gene Delivery System that is Controlled by the Tumor Microenvironment", Gene Therapy, 4:791-796.
-	СМ	Levine, 1995, Recombinant and Live Oral Salmenella typh/ Vaccines , NH+ Project Number 5 R01 A/29474-66.
	CN	Lindgren et al., 1996, "Macrophage killing is an essential virulence mechanism of Salmonella typhimurium", PNAS, <u>93(</u> 9) 4197-4201
	со	Loppnow et al., 1990, "Cytokine Induction by Lipopolysaccharide (LPS) Corresponds to Lethal Toxicity and is Inhibited by Nontoxic Rhodobacter capsulatus LPS", Infect. Immun. 58:3743-3750
	СР	Low et al., 1999, "VNP20009, a genetically modified Salmonella Typhimurium for treatment of solid tumors", Proc. Amer. As For Can. Res. 40:87
	ca	Low et al., 1999, "Lipid A mutant Salmonella with suppressed virulence and TNFa induction retain tumor-targeting in vivo", Nature Biotechnology, 17:37-41.
	CR	Lytvyn et al., 1992, "Comparison of the Thymidine Kinase Genes from Three Entomopoxviruses", J. Gen. Virol. 73:3235-324
	cs	Macnab, 1992, "Genetics and Biogenesis of Bacterial Flagella", Ann. Rev. Genet. 26:131-158.
	ст	Mahan et al., 1993, "Selection of Bacterial Virulence Genes that are Specifically Induced in Host Tissues", Science <u>259</u> :686
	cu	Marr et al., 1997, "Tumor immunothereapy using an adenoviral vector expressing a membrane-bound mutant of murine TNF alpha", Gene Therapy 4(11): Abstract
ers	cv	McLaughlin et al., 1979, "Synergistic Activity of Components of Mycobacteria and Mutant Selmonella in Causing Regression of Line-10 Tumors in Guinea Pigs", Cancer Res. 39:1766-1771
Kns.	-cw-	Michalek, 1994, "Genetically Engineered Oral Vaccines and Caries Immunity", Abstract, NIH Project Number 5 R01 DE09081-05
		RR 2/6/04 NY2-1173442

# OT 1 4 2003 55

# RECEIVED

### NOV 0 7 2003

**TECH CENTER 1600/2900** 

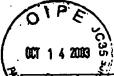
Sheet 4 of 5

		EUN GENTER 1600/2900
RA	S CX	Militer, 1995, "Entry into Sukaryotic Cells by Salmonella and Yersinis", NIH Project Number 5 K04 Al01230-02
TRA	CY	Miller et al., 1992, "An Unusual pagC::TnphoA Mutation Leads to an Invasion- and Virulence-Defective Phenotype in Salmonellae", Infect. Immun. 60:3763-3770
	cz	Miller et al., 1989, "A Two-Component Regulatory System (phoP phoQ) Controls Salmonella typhimurium Virulence", Proc. Natl. Acad. Sci. USA 86:5054-5058
	DA	Minton et al., 1995, "Chemotherapeutic Tumor Targeting Using Clostridial Spores", FEMS Micro. Rev. 17:357-364
	DB	Möse and Möse, 1963, "Oncolysis by Clostridia. I. Activity of Clostridium butyricum (M-55) and Other Nonpathogenic . Clostridia Against the Ehrlich Carcinoma", Cancer Res. 24:212-216
	DC	Mullen et al., 1992, "Transfer of the Bacterial Gene for Cytosine Deaminase to Mammalian Cells Confers Lethal Sensitivity to 5-Fluorocytosine: a Negative Selection System", Proc. Natl. Acad. Sci USA 89:33-37
$T_{-}$	DD	Nauts et al., 1953, "A Review of the Influence of Bacterial Infection and of Bacterial Products (Coley's Toxins) on Malignant Tumors in Man", Acta Medica Scandinavica 145 (Suppl. 276):1-105
	DE	O'Callaghan et al., 1988, "Characterization of aromatic and purine dependent Salmonella typhimurium: Attenuation, persistence, and ability induce protective immunity in BALB/c mice", Infact. And Immun, 56:419-423
	DF	Pan et al., 1995, * A Recombinant Listeria monocytogenes Vaccine Expressing a Model Turnor Antigen Protects Mice Against Lethal Turnor Cell Challenge and Causes Regression of Established Turnors*, Nature Medicine 1:471-477
	DG	Parker et al., 1947, "Effect of Histolyticus Infection and Toxin on Transplantable Mouse Tumors", Proc. Soc. Exp. Biol. Med. 16124:461-467
	DH	Pawelek et al., 1995, "Macrophage Characteristics of Metastatic Melanoma", J. Invest. Dermatol. 104:605 (Abstract 304)
	DI	Pawelek et al., 1997, "Tumor-targeted Salmonella as a Novel Anti-cancer Vector", Cancer Res., 57:4537-4544.
	LO LO	Pidherney et al., 1993, "In vitro and in vivo Tumoricidal Properties of a Pathogenic Free-Living Amoeba", Cancer Letters 72:91-98
	DK	Platt et al., 2000, "Anti tumor effects of genetically engineered Salmonella in combinationwithradiation ", Eur. J. Cancer, 36: 2397-2402
	DL	Pugsley, 1988, "Protein Secretion Across the Outer Membrane of Gram-Negative Bacteria" In: <u>Protein Transfer and Organelle Biogenesis</u> , D and Robbins (eds.), Academic Press, Inc., Harcourt Brace Jovanovich, Publishers, San Diego, pp. 607-652
	DM	Raue and Cashel, 1975, "Regulation of RNA Synthesis in Escherichia coli", Biochimica et Biophysica Acta 383:290-304
	DN	Reinhard et al., 1950, "Chemotherapy of Malignant Neoplastic Diseases", JAMA 142:383-390
	DO	Saltzman et al., 1996, "Attenuated Salmonella typhimurium Containing Interleukin-2 Decreases MC-38 Hepatic Metastases: Novel Anti-Tumor Agent", Cancer Biotherapy and Radiopharmaceuticals 11:145-153
	DP	Schafer et al., 1992, "Induction of a Cellular Immune Response to a Foreign Antigen by a Recombinant Listeria monocytogenes Vaccine", J. Immunol. 149:53-59
	DQ	Schlechte and Elbe, 1988, "Recombinant Plasmid DNA Variation of <i>Clostridium oncolyticum</i> - Model Experiments of Cancerostatic Gene Transfer*, Zbl. Bakt. Hyg. A <u>268</u> :347-356
	DR	Schlechte et al., 1982, "Chemotherapy for Tumours Using Clostridial Oncolysis, Antibiotics and Cyclophosphamide: Model Trial on the UVT 15264 Tumor", Arch. Geschwulstforsch. 52:41-48
	DS	Shaw et al., 1991, "The Human Dioxin-Inducible NAD(P)H: Quinone Oxidoreductase cDNA-Encoded Protein Expressed in COS-1 Cells is Identical to Diaphorase 4", Eur. J. Biochem. 195:171-176
	DT	Sizemore et al., 1995, "Attenuated Shigella as a DNA Delivery Vehicle for DNA-Mediated Immunization", Science 270:299-302
	DU	Sizemore et al., 1997, "Interaction- of salmonella typhi strains with cultured human monocyte-derived macrophages", Infect Immunity 65:309-312
	DV	Slauch et al., 1994, "In vivo Expression Technology for Selection of Bacterial Genes Specifically Induced in Host Tissues", Meth. Enzymol. 235:481-492
	DW	Somerville et al., 1996, "A Novel Escherichia coli Lipid A Mutant that Produces an Antiinflammatory Lipopolysaccharide", J Clin. Invest. 97:359-365
	DX	Sosnowski et al., 1994, "Complications of Bacillus Calmette-Guerin (BCG) Immunotherapy in Superficial Bladder Cancer", Comp. Ther. 20:695-701
2113	DY	Stemberg and Maurer, 1991, "Bacteriophage mediated generalized transduction in Escherichia coli and Salmonella
	<u> </u>	typhimurium*, Methods in Enzymology, 204;18-43  NY2 - 1173442:

PRS

2/6/04

NY2 - 1173442.1



201	RADEM	RY OZ	Su et al., 1992, "Extracellular Export of Shiga Toxin B-Subunit/Haemolysin A (C-terminus) Fusion Protein Expressed in Salmonella typhimurium aroA-Mutant and Stimulation of B-Subunit Specific Antibody Responses in Mice", Microbial Pathogenesis 13:465-476			
E		EA	Sunshine et al., 1997, "Mutation of the htrB Gene in Virulent Selmonella typhimurium Strain by Intergeneric Transduction: Strain Construction and Phenotypic Characterization", J. Bacteriol., 179(17):5521-5533.			
		EB	Sznol et al., 2000, "Use of preferentially replicating bacteria for treatment of cancer", J. Clinical Invest., 105:1027-1030			
		EC	Takayma et al., 1989, "Diphosphoryl Lipid A from <i>Rhodopseudomonas sphaeroides</i> ATCC 17023 Blocks Induction of Cachectin in Macrophages by Lipopolysaccharide", Infect. Immun. <u>57</u> :1336-1338			
		ED	Thiele et al., 1963, "Oncolysis by Clostridia. IV. Effect of Nonpathogenic Clostridial Spores in Normal and Pathological Tissues", Cancer Res. 24:234-238			
		EE	Thiele et al., 1963, "Oncolysis by Clostridia. III. Effects of Clostridia and Chemotherapeutic Agents on Rodent Turnors", Cancer Res. 24:222-232			
		EF	Tuomanen, 1993, "Subversion of Leukocyte Adhesion Systems by Respiratory Pathogens", Am. Soc. Microbiol. 59:292-29			
		EG	Vaara et al., 1999, "Outer membrane permeability barrier in Escherichia coli mutants that are defective in the late acyltransferases of lipid A biosynthesis", J. Bacteriol, 43(6):1459-1462			
	:	EH	Vinopal, 1987, "Selectable Phenotypes", from <u>Escherichia coli and Salmonella typhimurium, Cellular and Molecular Biology,</u> Neldhardt et al. (ed.), pp. 990-1015			
	•	ΕI	Wolfe et al., 1971, "Salmonellosis in Patients with Neoplastic Disease", Arch. Intern. Med. 128:547-554			
		EJ	Zheng et al., 1997, "Attenuated Salmonella typhimurium inhibited umor metastasis in vivo" Proc Amer Assoc. Can Res. 38:9			
$\prod$		ΕT	Somerville et al., 1999, "Escherichia coli msbB Gene as a Virulence Factor and a Therapeutic Target", Infect. And Immunity 67(12): 6583-6590			
		EU	Lee et al., 2000, "Comparative evaluation of theacute toxic effects in monkeys, pigs, and mice of a genetically engineered Salmonella strain (VNP20009) being developed as an anti-tumor agent", Int. J. of Toxicology, 19:19-25			
		EV	Luo et al., 1999, "Genetically modified Salmonella typhimurium inhibited growth of primary tumors and metastases", Abstract #3146. Proc. Amer. Assoc. For Cancer Res. 40:476			
		EW	Tacket et al., 1992, "Comparison of the safety and immunogenicity of aroC aroD and cya crp Salmonella typhi strains in adult volunteers", Infect. Immun., 60:536-541			
		EX	Hohmann et al., 1996, "Evaluation of a phoP/phoQ-deleted, aroA-deleted live oral Salmonetta typhi vaccine strain in human volunteers", Vaccine 14:19-24			
		EY	Tacket et al., 1997, "Safety of live oral Salmonella typhi vaccine strains with deletions in htrA and aroCaroD and immune response in humans", Infect. Immun, 65(2):452-456			
R	ns	EZ	Tacket et al., 2000, "Phase 2 clinical trial of attentuated Salmonella enterica serovar typhi oral live vector vaccine CVD 908-htrA in US volunteers", Infect. Immun. 68(3):1196-1201			

EXAMINER	RAS.	DATE CONSIDERED	2/6/04
	/ Cr		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.